IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Sitagliptin Phosphate ('708 & '921) Patent Litigation	C.A. No. 19-md-2902-RGA
MERCK SHARP & DOHME CORP., *Plaintiff,* v. MACLEODS PHARMACEUTICALS LIMITED, and MACLEODS PHARMA USA, INC., *Defendants*.	C.A. No. 19-cv-316-RGA

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF'S FIRST AMENDED COMPLAINT

Defendants Macleods Pharmaceuticals Limited and Macleods Pharma USA, Inc. (collectively, "Macleods"), by and through their attorneys, answer the First Amended Complaint filed by Plaintiff Merck Sharp & Dohme Corp. ("Merck") as follows:

AS TO THE NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendants' submission of Abbreviated New Drug Application ("ANDA") Nos. 211073 and 212338 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUVIA® (sitagliptin phosphate) and JANUMET® (metformin hydrochloride; sitagliptin phosphate) prior

to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent") and U.S. Patent No. 8,414,921 ("the '921 patent").

ANSWER:

Macleods admits that Merck purports to bring this action under the patent laws of the United States and under the Federal Declaratory Judgment Act and admits that the recited ANDA applications seek FDA approval to commercially manufacture, use, offer for sale, sell, and/or import versions of sitagliptin phosphate oral tablets and metformin hydrochloride and sitagliptin tablets. Macleods denies any patent infringement as alleged by Plaintiff.

AS TO BACKGROUND

2. Macleods Pharmaceuticals Limited notified Merck by letter dated November 20, 2018 ("Macleods's '073 Notice Letter") that it had submitted to the FDA ANDA No. 211073 ("Macleods's '073 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin phosphate oral tablets ("Macleods's '073 ANDA Product") prior to the expiration of the '708 patent.

ANSWER:

Admitted.

3. On information and belief, Macleods's '073 ANDA Product is a generic version of Merck's JANUVIA®.

ANSWER:

Macleods states that ANDA No. 211073 refers to JANUVIA® as the reference listed drug. To the extent that there are any remaining factual allegations in Paragraph 3, Macleods denies them.

4. Macleods Pharmaceuticals Limited and Macleods Pharma USA, Inc. notified Merck by letter dated November 20, 2018 ("Macleods's '338 Notice Letter") that it had submitted to the FDA ANDA No. 212338 ("Macleods's '338 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic metformin hydrochloride and sitagliptin phosphate oral tablets ("Macleods's '338 ANDA Product") prior to the expiration of the '708 patent and the '921 patent.

ANSWER:

Admitted.

5. On information and belief, Macleods's '338 ANDA Product is a generic version of Merck's JANUMET®.

ANSWER:

Macleods states that ANDA No. 212338 refers to JANUMET® as the reference listed drug. To the extent that there are any remaining factual allegations in Paragraph 5, Macleods denies them.

6. Macleods's '073 Notice Letter and Macleods's '338 Notice Letter are collectively referred to herein as "Macleods's Notice Letters." Macleods's '073 ANDA and Macleods's '338 ANDA are collectively referred to herein as "Macleods's ANDAs." Macleods's '073 ANDA Product and Macleods's '338 ANDA Product are collectively referred to herein as "Macleods's ANDA Products."

ANSWER:

Paragraph 6 contains no factual assertion that requires an admission or denial.

AS TO THE PARTIES

7. Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

ANSWER:

Macleods is without knowledge or information to determine the truth or falsity of the allegations in Paragraph 7 of the Complaint and on that basis denies them.

8. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

ANSWER:

Admitted.

9. Merck is the holder of NDA No. 22044 for JANUMET® (metformin hydrochloride; sitagliptin phosphate), which has been approved by the FDA.

ANSWER:

Admitted.

10. On information and belief, defendant Macleods Pharmaceuticals Limited ("Macleods Limited") is a corporation organized and existing under the laws of India, having its corporate offices and principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India. On information and belief, Macleods Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Macleods Pharma USA, Inc.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059. Macleods admits that Macleods Pharmaceuticals Limited is in the business of manufacturing generic versions of branded pharmaceutical drugs. Macleods admits that Macleods Pharma USA, Inc. is a subsidiary of Macleods Pharmaceuticals Limited that sells generic versions of branded pharmaceutical drugs. Macleods denies the remaining allegations in Paragraph 10.

11. On information and belief, defendant Macleods Pharma USA, Inc. ("Macleods Pharma") is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, NJ, 08536. On information and belief, Macleods Pharma is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

ANSWER:

Macleods admits that Macleods Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, NJ 08536. Macleods further admits that Macleods Pharma USA, Inc. is in the business of selling generic versions of branded pharmaceutical drugs for the U.S. market. Macleods denies the remaining allegations in Paragraph 11.

12. On information and belief, Macleods Pharma is a wholly owned subsidiary of Macleods Limited. Macleods Limited and Macleods Pharma are collectively referred to herein as "Macleods."

ANSWER:

Macleods admits that Macleods Pharma USA, Inc. is a wholly owned subsidiary of Macleods Pharmaceuticals Limited.

13. On information and belief, Macleods Limited and Macleods Pharma acted in concert to prepare and submit Macleods's ANDAs to the FDA.

ANSWER:

The allegations of Paragraph 13 state legal conclusions that do not require a response. Macleods admits that Macleods Pharmaceuticals Limited acted to prepare and submit Macleods' ANDAs to the FDA and denies any other factual allegations of Paragraph 13.

14. On information and belief, Macleods Limited and Macleods Pharma know and intend that upon approval of Macleods's ANDAs, Macleods will manufacture, market, sell, and distribute Macleods's ANDA Products throughout the United States, including in Delaware. On information and belief, Macleods Limited and Macleods Pharma are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Macleods's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Macleods Limited and Macleods Pharma participated, assisted, and cooperated in carrying out the acts complained of herein.

ANSWER:

Macleods lacks knowledge or information sufficient to form a belief as to the allegations in the first sentence of Paragraph 14 and therefore denies them. The other allegations of Paragraph 14 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 14, Macleods denies them.

15. On information and belief, following any FDA approval of Macleods's ANDAs, Macleods Limited and Macleods Pharma will act in concert to distribute and sell Macleods's ANDA Products throughout the United States, including within Delaware.

ANSWER:

The allegations of Paragraph 15 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 15, Macleods lacks knowledge or information sufficient to form a belief as to such allegations and therefore denies them.

AS TO JURISDICTION

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER:

Admitted.

17. This Court has personal jurisdiction over Macleods.

ANSWER:

Paragraph 17 states a legal conclusion to which no response is required. However, Macleods does not contest personal jurisdiction in this Court for purposes of this civil action only.

18. Macleods Limited is subject to personal jurisdiction in Delaware because, among other things, Macleods Limited, itself and through its wholly owned subsidiary Macleods Pharma, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Macleods Limited, itself and through its wholly owned subsidiary Macleods Pharma, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including

in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Macleods Limited is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Macleods Pharma and therefore the activities of Macleods Pharma in this jurisdiction are attributed to Macleods Limited.

ANSWER:

Macleods denies the allegations of Paragraph 18 as phrased but does not contest personal jurisdiction over Macleods Pharmaceuticals Limited in this Court for the purposes of this civil litigation only.

19. Macleods Pharma is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Macleods Pharma is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Macleods Pharma develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

ANSWER:

Macleods denies the allegations of Paragraph 19 as phrased but does not contest personal jurisdiction over Macleods Pharma USA, Inc. in this Court for the purposes of this civil litigation only.

20. In addition, this Court has personal jurisdiction over Macleods because Macleods Limited and Macleods Pharma regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., H. Lundbeck A/S v. Macleods Pharms. Ltd.*, No. 18-91, D.I. 13 (D. Del. Mar. 30, 2018); *Biogen Int'l GmbH v. Macleods Pharms. Ltd.*, No. 17- 857, D.I. 7 (D. Del. July 17, 2017); *Amgen, Inc. v. Macleods Pharms. Ltd.*, No. 17-817-GMS, D.I. 9 (D. Del. July 17, 2017); *Bristol-Myers Squibb Co. v. Macleods Pharms. Ltd.*, No. 17-405- LPS, D.I. 8 (D. Del. June 28, 2017); *Bayer Pharma AG v. Macleods Pharms. Ltd.*, No. 15-464- GMS, D.I. 14 (D. Del. Aug. 31, 2015).

ANSWER:

Macleods denies the allegations of Paragraph 20 as phrased but does not contest personal jurisdiction in this Court for the purposes of this civil litigation only.

21. On information and belief, if Macleods's ANDAs are approved, Macleods will manufacture, market, sell, and/or distribute Macleods's ANDA Products within the United States, including in Delaware, consistent with Macleods's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Macleods regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Macleods's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Macleods's ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware.

Each of these activities would have a substantial effect within Delaware and would constitute infringement of Merck's patent in the event that Macleods's ANDA Products are approved before the patent expires.

ANSWER:

Macleods denies the allegations of Paragraph 21 as phrased but does not contest personal jurisdiction in this Court for the purposes of this civil litigation only.

22. On information and belief, Macleods derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Macleods and/or for which Macleods Limited and/or Macleods Pharma is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Macleods Limited and/or Macleods Pharma is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in Delaware.

ANSWER:

Macleods denies the allegations of Paragraph 22 as phrased but does not contest personal jurisdiction in this Court for the purposes of this civil litigation only.

AS TO VENUE

23. Merck incorporates each of the preceding paragraphs 1–22 as if fully set forth herein.

ANSWER:

Macleods incorporates each of its responses to Paragraphs 1-22 as if fully set forth herein.

24. Venue is proper in this district as to Macleods Limited under 28 U.S.C. § 1391 because Macleods Limited is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

ANSWER:

Paragraph 24 states a legal conclusion to which no response is required. Macleods denies the remaining allegations of Paragraph 24 as phrased but does not contest venue in this district as to Macleods Pharmaceuticals Limited for the purposes of this civil litigation only.

25. Venue is proper in this district as to Macleods Pharma under 28 U.S.C. § 1400(b) because Macleods Pharma is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

ANSWER:

Paragraph 25 states a legal conclusion to which no response is required. Macleods denies the remaining allegations of Paragraph 25 as phrased but does not contest venue in this district as to Macleods Pharma USA, Inc. for the purposes of this civil litigation only.

AS TO THE '708 PATENT

26. Merck incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

ANSWER:

Macleods incorporates each of its responses to Paragraphs 1-25 as if fully set forth herein.

27. The inventors named on the '708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr.

ANSWER:

Macleods admits that Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicki K. Vydra, and Robert M. Wenslow, Jr. are listed as inventors on the face of the '708 patent. To the extent that there are any remaining factual allegations in Paragraph 27, Macleods lacks knowledge or information sufficient to form a belief as to such allegations and therefore denies them.

28. The ’708 patent, entitled “Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor” (attached as Exhibit A), was duly and legally issued on February 5, 2008.

ANSWER:

Macleods admits only that the ’708 patent was issued on February 5, 2008, and is entitled “Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor,” and that what appears to be a copy of the ’708 patent is attached as Exhibit A to the Complaint. Macleods denies that the ’708 patent was duly and legally issued.

29. Merck is the owner and assignee of the ’708 patent.

ANSWER:

Macleods states that the U.S. Patent and Trademark Office assignment database lists MERCK SHARP & DOHME CORP. as the assignee of the ’708 patent. Macleods lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 29 and therefore denies them.

30. The ’708 patent claims, *inter alia*, a dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5- trifluorophenyl) butan-2-amine of structural formula I, or a hydrate thereof, as recited in claim 1 of the ’708 patent.

ANSWER:

The allegations of Paragraph 30 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 30, Macleods states that claim 1 of the ’708 patent speaks for itself.

31. JANUVIA®, as well as methods of using JANUVIA®, are covered by one or more claims of the ’708 patent, including claim 1 of the ’708 patent, and the ’708 patent has been listed in connection with JANUVIA® in the FDA’s Orange Book.

ANSWER:

Macleods admits that the'708 patent has been listed in connection with JANUVIA® in the FDA's Orange Book. The remaining allegations of Paragraph 31 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 31, Macleods lacks knowledge or information sufficient to form a belief as to those allegations and therefore denies them.

32. JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUMET® in the FDA's Orange Book.

ANSWER:

Macleods admits that the'708 patent has been listed in connection with JANUMET® in the FDA's Orange Book. The remaining allegations of Paragraph 32 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 32, Macleods lacks knowledge or information sufficient to form a belief as to those allegations and therefore denies them.

AS TO THE '921 PATENT

33. Merck incorporates each of the preceding paragraphs 1–32 as if fully set forth herein.

ANSWER:

Macleods incorporates its responses to each of the preceding Paragraphs 1-32 as if fully set forth herein.

34. The inventors named on the '921 patent are Ashkan Kamali, Laman Alani, Kyle A. Fliszar, Soumojeet Ghosh, and Monica Tijerina.

ANSWER:

Macleods admits that Ashkan Kamali, Laman Alani, Kyle A. Fliszar, Soumojeet Ghosh, and Monica Tijerina are listed as inventors on the face of the '921 patent. To the extent that there are any remaining factual allegations in Paragraph 34, Macleods lacks knowledge or information sufficient to form a belief as to such allegations and therefore denies them.

35. The '921 patent, entitled "Pharmaceutical Compositions of Combinations of Dipeptidyl Peptidase-4 Inhibitors with Metformin" (attached as Exhibit B), was duly and legally issued on April 9, 2013.

ANSWER:

Macleods admits only that the '921 patent was issued on April 9, 2013, and is entitled "Pharmaceutical Compositions of Combinations of Dipeptidyl Peptidase-4 Inhibitors with Metformin," and that what appears to be a copy of the '921 patent is attached as Exhibit B to the First Amended Complaint. Macleods denies that the '921 patent was duly and legally issued.

36. Merck is the owner and assignee of the '921 patent.

ANSWER:

Macleods states that the U.S. Patent and Trademark Office assignment database lists MERCK SHARP & DOHME CORP. as the assignee of the '921 patent. Macleods lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 36 and therefore denies them.

37. The '921 patent claims, *inter alia*, a pharmaceutical composition comprising: (a) about 3 to 20% by weight of sitagliptin, or a pharmaceutically acceptable salt thereof, (b) about 25 to 94% by weight of metformin hydrochloride; (c) about 0.1 to 10% by weight of a lubricant; (d)

about 0 to 35% by weight of a binding agent; € about 0.5 to 1% by weight of a surfactant; and (f) about 5 to 15% by weight of a diluent, as recited in claim 1 of the ’921 patent.

ANSWER:

The allegations of Paragraph 37 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 37, Macleods states that claim 1 of the ’921 patent speaks for itself.

38. JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the ’921 patent, including claim 1 of the ’921 patent, and the ’921 patent has been listed in connection with JANUMET® in the FDA’s Orange Book.

ANSWER:

Macleods admits that the’921 patent has been listed in connection with JANUMET® in the FDA’s Orange Book. The remaining allegations of Paragraph 38 state legal conclusions that do not require a response. To the extent that there are any remaining factual allegations in Paragraph 38, Macleods lacks knowledge or information sufficient to form a belief as to those allegations and therefore denies them.

AS TO COUNT I – INFRINGEMENT OF THE ’708 PATENT (MACLEODS’S ’703 ANDA PRODUCT)

39. Merck incorporates each of the preceding paragraphs 1–38 as if fully set forth herein.

ANSWER:

Macleods incorporates its responses to each of the preceding Paragraphs 1-38 as if fully set forth herein.

40. In Macleods's '073 Notice Letter, Macleods notified Merck of the submission of Macleods's '073 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Macleods's '073 ANDA Product prior to the expiration of the '708 patent.

ANSWER:

Macleods admits only that Macleods Pharmaceuticals Limited notified Merck that Macleods Pharmaceuticals Limited had submitted to the FDA ANDA No. 211073 for Macleods' ANDA Product by letter dated November 20, 2018, and that ANDA No. 211073 requests FDA's marketing approval of Macleods' ANDA Product prior to the expiration of the '708 patent. Macleods denies the remaining allegations in Paragraph 40.

41. In Macleods's '073 Notice Letter, Macleods also notified Merck that, as part of its ANDA, Macleods had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Macleods submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods's '073 ANDA Product.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Limited notified Merck in its letter dated November 20, 2018, that, as part of its ANDA No. 211073, it filed certifications pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) with respect to the '708 patent. Macleods further admits that it filed certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid,

unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods' '073 ANDA Product.

42. In Macleods's '073 Notice Letter, Macleods stated that Macleods's '073 ANDA Product contains sitagliptin phosphate as an active ingredient.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Limited notified Merck in its letter dated November 20, 2018, that the active ingredient in its ANDA No. 211073 product is sitagliptin phosphate. Macleods denies the remaining allegations of Paragraph 42.

43. Macleods's '073 ANDA Product, and the use of Macleods's '073 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Macleods's '073 ANDA Product.

ANSWER:

The allegations of Paragraph 43 state legal conclusions that require no response. To the extent that there are any remaining factual allegations in Paragraph 43, Macleods denies them.

44. In Macleods's '073 Notice Letter, Macleods did not contest infringement of claim 1 of the '708 patent.

ANSWER:

Denied.

45. Macleods's submission of Macleods's '073 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's '073 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

46. On information and belief, Macleods will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's '073 ANDA Product immediately and imminently upon approval of its ANDA.

ANSWER:

Macleods lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 46 and therefore denies them.

47. The manufacture, use, sale, offer for sale, or importation of Macleods's '073 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

ANSWER:

Denied.

48. On information and belief, the manufacture, use, sale, offer for sale, or importation of Macleods's '073 ANDA Product in accordance with, and as directed by its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

ANSWER:

Denied.

49. On information and belief, Macleods plans and intends to, and will, actively induce infringement of the '708 patent when Macleods's '073 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Macleods's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

ANSWER:

Denied.

50. On information and belief, Macleods knows that Macleods's '073 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Macleods's '073 ANDA Product is not a staple article or commodity of commerce, and that Macleods's '073 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Macleods plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Macleods's '073 ANDA.

ANSWER:

The allegations of Paragraph 50 state legal conclusions that require no response. To the extent that there are any remaining factual allegations in Paragraph 50, Macleods denies them.

51. Notwithstanding Macleods's knowledge of the claims of the '708 patent, Macleods has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Macleods's '073 ANDA Product with its product labeling following FDA approval of Macleods's '073 ANDA prior to the expiration of the '708 patent.

ANSWER:

Macleods admits that it has knowledge of the claims of the '708 patent. Macleods further admits that it filed ANDA No. 211073 seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Macleods' ANDA product. Macleods denies the remaining allegations of Paragraph 51.

52. The foregoing actions by Macleods constitute and/or will constitute infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and contribution to the infringement by others of the ’708 patent.

ANSWER:

Denied.

53. On information and belief, Macleods has acted with full knowledge of the ’708 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and/or contribution to the infringement by others of the ’708 patent.

ANSWER:

Macleods admits that it has knowledge of the’708 patent. Macleods denies the remaining allegations of Paragraph 53.

54. Merck will be substantially and irreparably damaged by infringement of the ’708 patent.

ANSWER:

Denied.

55. Unless Macleods is enjoined from infringing the ’708 patent, actively inducing infringement of the ’708 patent, and contributing to the infringement by others of the ’708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

ANSWER:

Denied.

AS TO COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT (MACLEODS'S '703 ANDA PRODUCT)

56. Merck incorporates each of the preceding paragraphs 1–55 as if fully set forth herein.

ANSWER:

Macleods incorporates each of its responses to Paragraphs 1-55 as if fully set forth herein.

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Macleods on the other regarding Macleods's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

ANSWER:

The allegations in Paragraph 57 state legal conclusions that require no response. Macleods denies Merck's allegations of infringement.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Macleods's '073 ANDA Product with its proposed labeling, or any other Macleods drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '708 patent, and that the claims of the '708 patent are valid.

ANSWER:

The allegations in Paragraph 58 state legal conclusions that require no response. Macleods denies Merck's allegations of infringement.

AS TO COUNT III – INFRINGEMENT OF THE '708 PATENT (MACLEODS'S '338 ANDA PRODUCT)

59. Merck incorporates each of the preceding paragraphs 1–58 as if fully set forth herein.

ANSWER:

Macleods incorporates each of its responses to Paragraphs 1-58 as if fully set forth herein.

60. In Macleods's '338 Notice Letter, Macleods notified Merck of the submission of Macleods's '338 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Macleods's '338 ANDA Product prior to the expiration of the '708 patent.

ANSWER:

Macleods admits only that Macleods Pharmaceuticals Limited notified Merck that Macleods Pharmaceuticals Limited had submitted to the FDA ANDA No. 212338 for Macleods' ANDA Product by letter dated November 20, 2018. Macleods further states that ANDA No. 212338 requests the FDA's marketing approval of Macleods' ANDA Product prior to the expiration of the '708 patent. Macleods denies the remaining allegations in Paragraph 60.

61. In Macleods's '338 Notice Letter, Macleods also notified Merck that, as part of its ANDA, Macleods had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Macleods submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods's '338 ANDA Product.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Limited notified Merck in its letter dated November 20, 2018, that, as part of its ANDA No. 212338, it filed certifications pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) with respect to the '708 patent. Macleods further admits that it filed certifications pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods' ANDA No. 212338 product.

62. In Macleods's '338 Notice Letter, Macleods stated that Macleods's '338 ANDA Product contains sitagliptin phosphate as an active ingredient.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Limited notified Merck in its letter dated November 20, 2018, that the active ingredient in its ANDA No. 212338 product is sitagliptin phosphate. Macleods denies the remaining allegations of Paragraph 62.

63. Macleods's '338 ANDA Product, and the use of Macleods's '338 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Macleods's '338 ANDA Product.

ANSWER:

The allegations of Paragraph 63 state legal conclusions that require no response. To the extent that there are any remaining factual allegations in Paragraph 63, Macleods denies them.

64. In Macleods's '338 Notice Letter, Macleods did not contest infringement of claim 1 of the '708 patent.

ANSWER:

Denied.

65. Macleods's submission of Macleods's '338 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's '338 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

66. On information and belief, Macleods will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's '338 ANDA Product immediately and imminently upon approval of its ANDA.

ANSWER:

Macleods lacks knowledge or information sufficient to form a belief as to the allegations of Paragraph 66 and therefore denies them.

67. The manufacture, use, sale, offer for sale, or importation of Macleods's '338 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

ANSWER:

Denied.

68. On information and belief, the manufacture, use, sale, offer for sale, or importation of Macleods's '338 ANDA Product in accordance with, and as directed by Macleods's proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

ANSWER:

Denied.

69. On information and belief, Macleods plans and intends to, and will, actively induce infringement of the '708 patent when Macleods's '338 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Macleods's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

ANSWER:

Denied.

70. On information and belief, Macleods knows that Macleods's '338 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Macleods's '338 ANDA Product is not a staple article or commodity of commerce, and that Macleods's '338 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and behlief, Macleods plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Macleods's '338 ANDA.

ANSWER:

The allegations of Paragraph 70 state legal conclusions that require no response. To the extent that there are any remaining factual allegations in Paragraph 70, Macleods denies them.

71. Notwithstanding Macleods's knowledge of the claims of the '708 patent, Macleods has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Macleods's '338 ANDA Product with its product labeling following FDA approval of Macleods's '338 ANDA prior to the expiration of the '708 patent.

ANSWER:

Macleods admits that it has knowledge of the claims of the '708 patent. Macleods further admits that it filed ANDA No. 212338 seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic versions of Macleods' ANDA product prior to the expiration of the '708 patent. Macleods denies the remaining allegations of Paragraph 71.

72. The foregoing actions by Macleods constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.

ANSWER:

Denied.

73. On information and belief, Macleods has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.

ANSWER:

Macleods admits that it has knowledge of the'708 patent. Macleods denies the remaining allegations of Paragraph 73.

74. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

ANSWER:

Denied.

75. Unless Macleods is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

ANSWER:

Denied.

AS TO COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT (MACLEODS'S '338 ANDA PRODUCT)

76. Merck incorporates each of the preceding paragraphs 1–75 as if fully set forth herein.

ANSWER:

Macleods incorporates each of its responses to Paragraphs 1-75 as if fully set forth herein.

77. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Macleods on the other regarding Macleods's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

ANSWER:

The allegations in Paragraph 77 state legal conclusions that require no response. Macleods denies Merck's allegations of infringement.

78. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Macleods's '338 ANDA Product with its proposed labeling, or any other Macleods drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '708 patent, and that the claims of the '708 patent are valid.

ANSWER:

The allegations in Paragraph 78 state legal conclusions that require no response. Macleods denies Merck's allegations of infringement.

AS TO COUNT V – INFRINGEMENT OF THE '921 PATENT (MACLEODS'S '338 ANDA PRODUCT)

79. Merck incorporates each of the preceding paragraphs 1–78 as if fully set forth herein.

ANSWER:

Macleods incorporates each of its responses to Paragraphs 1-78 as if fully set forth herein.

80. In Macleods's '338 Notice Letter, Macleods notified Merck of the submission of Macleods's '338 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Macleods's '338 ANDA Product prior to the expiration of the '921 patent.

ANSWER:

Macleods admits only that Macleods Pharmaceuticals Limited notified Merck that Macleods Pharmaceuticals Limited had submitted to the FDA ANDA No. 212338 for Macleods' ANDA Product by letter dated November 20, 2018. Macleods further states that ANDA No. 212338 requests the FDA's marketing approval of Macleods' ANDA Product prior to the expiration of the '921 patent. Macleods denies the remaining allegations in Paragraph 80.

81. In Macleods's '338 Notice Letter, Macleods also notified Merck that, as part of its ANDA, Macleods had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '921 patent. On information and belief, Macleods submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '921 patent is invalid, unenforceable, and/or will not be

infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods's '338 ANDA Product.

ANSWER:

Macleods admits that Macleods Pharmaceuticals Limited notified Merck in its letter dated November 20, 2018, that, as part of its ANDA No. 212338, it filed certifications pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) with respect to the '921 patent. Macleods further admits that it filed certifications pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) asserting that the '921 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods' ANDA No. 212338 product.

82. Macleods's '338 ANDA Product, and the use of Macleods's '338 ANDA Product, are covered by one or more claims of the '921 patent, including at least claim 1 of the '921 patent, because the composition of Macleods's '338 ANDA Product includes the same or equivalent ingredients as recited in claim 1 of the '921 patent in the same or equivalent amounts.

ANSWER:

The allegations of Paragraph 82 state legal conclusions that require no response. To the extent that there are any remaining factual allegations in Paragraph 82, Macleods denies them.

83. Macleods's submission of Macleods's '338 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's '338 ANDA Product before the expiration of the '921 patent was an act of infringement of the '921 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

84. On information and belief, Macleods will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's '338 ANDA Product immediately and imminently upon approval of its ANDA.

ANSWER:

Macleods lacks knowledge or information sufficient to form a belief as to the allegations of Paragraph 84 and therefore denies them.

85. The manufacture, use, sale, offer for sale, or importation of Macleods's '338 ANDA Product would infringe one or more claims of the '921 patent, including at least claim 1 of the '921 patent.

ANSWER:

Denied.

86. On information and belief, the manufacture, use, sale, offer for sale, or importation of Macleods's '338 ANDA Product in accordance with, and as directed by its proposed product labeling would infringe one or more claims of the '921 patent, including at least claim 1 of the '921 patent.

ANSWER:

Denied.

87. On information and belief, Macleods plans and intends to, and will, actively induce infringement of the '921 patent when Macleods's '338 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Macleods's activities will be done with knowledge of the '921 patent and specific intent to infringe that patent.

ANSWER:

Denied.

88. On information and belief, Macleods knows that Macleods's '338 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '921 patent, that Macleods's '338 ANDA Product is not a staple article or commodity of commerce, and that Macleods's '338 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Macleods plans and intends to, and will, contribute to infringement of the '921 patent immediately and imminently upon approval of Macleods's '338 ANDA.

ANSWER:

The allegations of Paragraph 88 state legal conclusions that require no response. To the extent that there are any remaining factual allegations in Paragraph 88, Macleods denies them.

89. Notwithstanding Macleods's knowledge of the claims of the '921 patent, Macleods has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Macleods's '338 ANDA Product with its product labeling following FDA approval of Macleods's '338 ANDA prior to the expiration of the '921 patent.

ANSWER:

Macleods admits that it has knowledge of the claims of the '921 patent. Macleods further admits that it filed ANDA No. 212338 seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic versions of Macleods' ANDA product prior to the expiration of the '921 patent. Macleods denies the remaining allegations of Paragraph 89.

90. The foregoing actions by Macleods constitute and/or will constitute infringement of the '921 patent; active inducement of infringement of the '921 patent; and contribution to the infringement by others of the '921 patent.

ANSWER:

Denied.

91. On information and belief, Macleods has acted with full knowledge of the ’921 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’921 patent; active inducement of infringement of the ’921 patent; and/or contribution to the infringement by others of the ’921 patent.

ANSWER:

Macleods admits that it has knowledge of the’921 patent. Macleods denies the remaining allegations of Paragraph 91.

92. Merck will be substantially and irreparably damaged by infringement of the ’921 patent.

ANSWER:

Denied.

93. Unless Macleods is enjoined from infringing the ’921 patent, actively inducing infringement of the ’921 patent, and contributing to the infringement by others of the ’921 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

ANSWER:

Denied.

AS TO COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’921 PATENT (MACLEODS’S ’338 ANDA PRODUCT)

94. Merck incorporates each of the preceding paragraphs 1–93 as if fully set forth herein.

ANSWER:

Macleods incorporates each of its responses to Paragraphs 1-93 as if fully set forth herein.

95. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Macleods on the other regarding Macleods's infringement, active inducement of infringement, and contribution to the infringement by others of the '921 patent.

ANSWER:

The allegations in Paragraph 95 state legal conclusions that require no response. Macleods denies Merck's allegations of infringement.

96. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Macleods's '338 ANDA Product with its proposed labeling, or any other Macleods drug product that is covered by or whose use is covered by the '921 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '921 patent, and that the claims of the '921 patent are valid.

ANSWER:

The allegations in Paragraph 96 state legal conclusions that require no response. Macleods denies Merck's allegations of infringement.

RESPONSE TO PRAYER FOR RELIEF

Macleods denies that Plaintiffs are entitled to the judgement or other relief prayed for in subparagraphs (a) through (k) under the heading "Prayer for Relief" in the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Plaintiff fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff fails to state any facts to support a claim upon which relief may be granted.

THIRD AFFIRMATIVE DEFENSE

Each asserted claim of the '708 patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116 and/or is invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

FOURTH AFFIRMATIVE DEFENSE

Macleods has not infringed, induced infringement of, or contributed to the infringement of, and Macleods will not infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable asserted claim of the '708 patent, either literally or under the doctrine of equivalents, through the submission of Macleods' ANDA No. 211073 and/or the importation, manufacture, use, offer for sale or sale of the product that is the subject of Macleods' ANDA No. 211073.

FIFTH AFFIRMATIVE DEFENSE

Macleods has not infringed, induced infringement of, or contributed to the infringement of, and Macleods will not infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable asserted claim of the '708 patent, either literally or under the doctrine of equivalents, through the submission of Macleods' ANDA No. 212338 and/or the importation, manufacture, use, offer for sale or sale of the product that is the subject of Macleods' ANDA No. 212338.

SIXTH AFFIRMATIVE DEFENSE

Each asserted claim of the '921 patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102,

103, 112 and/or 116 and/or is invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

SEVENTH AFFIRMATIVE DEFENSE

Macleods has not infringed, induced infringement of, or contributed to the infringement of, and Macleods will not infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable asserted claim of the '921 patent, either literally or under the doctrine of equivalents, through the submission of Macleods' ANDA No. 212338 and/or the importation, manufacture, use, offer for sale or sale of the product that is the subject of Macleods' ANDA No. 212338.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to seek injunctive relief against Macleods because Plaintiff's alleged damages are not immediate or irreparable, and therefore Plaintiff has an adequate remedy at law. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

NINTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to attorney's fees against Macleods because Plaintiff has not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

TENTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiff from recovering any costs associated with this action.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's allegations are barred, in whole or in part, by the doctrines of waiver, estoppel and/or prosecution history estoppel.

TWELFTH AFFIRMATIVE DEFENSE

Macleods reserves the right to assert additional affirmative defenses that may be developed or revealed during discovery.

COUNTERCLAIMS

In further response to the Complaint, Macleods alleges the following counterclaims, without prejudice to any denial in its Answer, and without admission to any allegation in the Complaint, unless otherwise explicitly admitted above, and without assuming any burden when such burden would otherwise be Plaintiff's.

Parties

1. Counterclaimant Macleods Pharmaceuticals Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Atlanta Arcade, Marol Church, Andheri (East), Mumbai, India 400059.

2. Counterclaimant Macleods Pharma USA, Inc. (collectively, both entities are referred to herein as "Macleods") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

3. Upon information and belief, Counterclaim Defendant Merck Sharp & Dohme Corp. ("Merck") is a corporation organized and existing under the laws of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

Jurisdiction and Venue

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202. Macleods' counterclaims relate to the claims made by Counterclaim Defendant Merck for patent infringement and arise under the patent laws of the United States, Title 35, United States Code.

5. This Court has personal jurisdiction over Merck by virtue of the fact that it conducts business in the State of Delaware, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with Delaware.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim Defendant Merck's filing of its action against Macleods. This Court may declare the rights and legal relation of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

The Controversy

7. Macleods holds Abbreviated New Drug Application ("ANDA") No. 211073 for sitagliptin phosphate oral tablet, eq 25 mg base, eq 50 mg base, and eq 100 mg base.

8. Macleods holds ANDA No. 212338 for metformin hydrochloride and sitagliptin tablets 500mg/50mg and 1000mg/50mg.

9. On or about February 13, 2019, Counterclaim Defendant Merck filed the present action against Macleods alleging infringement of United States Patent No. 7,326,708 ("the '708 patent"). There is a real, substantial, and continuing justiciable controversy between the parties because of the commencement by Counterclaim Defendant of its action and the filing by Macleods of ANDA Nos. 211073 and 212338 with certifications that the '708 patent is invalid, unenforceable and/or will not be infringed by the manufacture, sale and use of the products of Macleods' ANDA Nos. 211703 and 212338.

10. On or about February 13, 2020, Counterclaim Defendant Merck filed a First Amended Complaint against Macleods additionally alleging infringement of United States Patent No. 8,414,921 ("the '921 patent"). There is a real, substantial, and continuing justiciable controversy between the parties because of the commencement by Counterclaim Defendant of its action and the filing by Macleods of ANDA No. 212338 with certifications that the '921 patent is

invalid, unenforceable and/or will not be infringed by the manufacture, sale and use of the products of Macleods' ANDA No. 212338.

11. The patents-in-suit effectively prevents approval of Macleods' ANDA Nos. 211703 and 212338 and the manufacture, sale, and use of the products that are the subject of Macleods' ANDA Nos. 211703 and 212338. Macleods and Merck have adverse legal interests with respect to the patents-in-suit of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT I
Declaratory Judgment of Invalidity of the '708 Patent

12. Macleods repeats and incorporates by reference Paragraphs 1 to 11 of its Counterclaims as if fully set forth herein.

13. Each and every asserted claim of United States Patent No. 7,326,708 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT II
Declaratory Judgment of Non-Infringement of the '708 Patent

14. Macleods repeats and incorporates by reference Paragraphs 1 to 11 of its Counterclaims as if fully set forth herein.

15. Macleods has not infringed, induced infringement, or contributed to the infringement, and Macleods will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 7,326,708.

COUNT III
Declaratory Judgment of Invalidity of the '921 Patent

16. Macleods repeats and incorporates by reference Paragraphs 1 to 11 of its Counterclaims as if fully set forth herein.

17. Each and every asserted claim of United States Patent No. 8,414,921 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT II
Declaratory Judgment of Non-Infringement of the '921 Patent

18. Macleods repeats and incorporates by reference Paragraphs 1 to 12 of its Counterclaims as if fully set forth herein.

19. Macleods has not infringed, induced infringement, or contributed to the infringement, and Macleods will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 8,414,921.

Macleods' Request for Relief

WHEREFORE, Macleods respectfully requests that:

(a) Judgment be entered that the First Amended Complaint against Macleods is dismissed with prejudice and that Plaintiffs/Counterclaim Defendants take nothing thereby;

(b) Judgment be entered that each claim of United States Patent No. 7,326,708 is invalid;

(c) The Court permanently enjoin Plaintiff/Counterclaim Defendant or any of its assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or

import of the products which are the subject of Macleods' ANDA Nos. 211703 and 212338 infringe or will infringe any valid claim of U.S. Patent No. 7,326,708.

(d) Judgment be entered that each claim of United States Patent No. 8,414,921 is invalid;

(e) The Court permanently enjoin Plaintiff/Counterclaim Defendant or any of its assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Macleods' ANDA No. 212338 infringe or will infringe any valid claim of U.S. Patent No. 8,414,921.

(f) This case be deemed an exceptional case within the meaning of 35 U.S.C. § 285.

(g) Macleods be awarded its reasonable costs and attorney fees; and

(h) The Court award Macleods such other and further relief as this Court may deem necessary, just and proper.

Respectfully submitted,

/s/ John M. Seaman

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